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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re application of: | Confirmation No. 7736 |
| RASHTCHIAN *et al.* | Art Unit: 1634 |
| Appl. No. 09/741,664 | Examiner: Arthur, L. |
| Filed: December 21, 2000 | Atty. Docket: 0942.3910003/BJD/AGU |
| For: **Stable Compositions for Nucleic Acid Amplification and Sequencing** | |

# First Supplemental Information Disclosure Statement



Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Following is information that may be considered material to the examination of above-identified application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The information provided herein is based upon the belief of, and upon information currently available to, Applicants' undersigned representative.

## *I. Statement of Facts for Consideration by the Examiner*

### *A. Outside Testing of Compositions*

Prior to August 14, 1996, Dr. Ayoub Rashtchian, one of the listed inventors, and his colleagues at Life Technologies, Inc. developed compositions. The compositions developed included compositions comprising one thermostable enzyme, as well as compositions comprising at least two thermostable enzymes (particularly one or more thermostable DNA polymerases). More than one year prior to February 14, 1997, but less than one year prior to August 14, 1996, Dr. Rashtchian and his colleagues provided samples of the compositions under development to

independent researchers outside of Life Technologies, Inc., to determine the usefulness of the compositions in a variety of technical applications.

Dr. Rashtchian and his colleagues identified approximately 30 scientists outside of Life Technologies, Inc., all of whom were within the United States, who could perform amplification and sequencing experiments within their own laboratories using the compositions that were under development. To this end, samples of the compositions under development were sent to these approximately 30 outside investigators, without cost to the investigators.

In addition to this U.S.-based experimental testing program, more than one year prior to August 14, 1996, samples of the compositions under development were sent to the European division of Life Technologies, Inc., to be evaluated by investigators in Europe. These samples were provided to investigators in Europe, without cost to the investigators.

The samples of the compositions that were sent to these outside investigators in the United States and in Europe were not labeled as to formulation or content. The documentation accompanying the samples provided to the outside investigators did not identify all of the active components that were present in the compositions. Upon receiving the samples, the outside investigators were provided only with the identities and concentrations of the ionic components of the aqueous compositions and with the identities of the enzymes present in the compositions. Upon receiving the samples, the outside investigators were *not* provided with information on the identities or concentrations of detergents present in the compositions, nor with the concentrations or concentration ratios of the enzymes present in the compositions.

Within two months following the provision of samples to the outside investigators, Dr. Rashtchian or one or more of his colleagues at Life Technologies, Inc., contacted each investigator via telephone to gather information from each investigator on the performance of the

samples of the compositions, and the range of applications in which the compositions were used by the investigators. In these telephonic discussions, each investigator was asked: (a) whether he or she had used the sampled compositions; (b) for what application(s) the compositions had been used by the investigator; and (c) how well the compositions had performed in the application(s) tested by the investigator, relative to compositions previously or usually used by the investigator. The data gathered from these telephonic surveys indicated that the majority of the investigators found the compositions acceptable for use in their respective application(s). As a result of these field tests, Dr. Rashtchian and his colleagues at Life Technologies, Inc., decided not to make any adjustments to the formulations of the compositions, believing that the results of the field tests indicated that the formulations that were sampled were optimal for use in the widest variety of nucleic acid amplification and sequencing applications.

***B. Sale of the Claimed Compositions***

During the above-noted field testing program, one of the investigators in the United States to whom a sample of the claimed compositions was sent indicated to Dr. Rashtchian or his colleagues at Life Technologies, Inc., that the investigator would like to purchase a bulk quantity of the compositions. In response, more than one year prior to February 14, 1997, but less than one year prior to August 14, 1996, a bulk quantity of a composition comprising a mixture of reagents (including at least one thermostable enzyme and at least one buffer salt) at working concentrations was sold to this investigator. Subsequent to receipt of the sold composition, the investigator contacted Life Technologies, Inc., and indicated that the composition was unacceptable in performance and requested replacement or refund. In response, more than one year prior to February 14, 1997, but less than one year prior to August 14, 1996, the composition

was reformulated into a composition comprising at least one thermostable enzyme, at least one buffer salt, at least one nonionic detergent, and at least one deoxynucleotide triphosphate, all at working concentrations. This reformulated composition was sent back to the same investigator more than one year prior to February 14, 1997, but less than one year prior to August 14, 1996, at no additional cost to the investigator. Upon follow-up questioning by personnel at Life Technologies, Inc., the investigator indicated that this reformulated composition performed adequately.

## *II. Additional Comments*

Listed on accompanying Form PTO-1449 is a document that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of this document is attached.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not an issue. Applicants have listed a publication date on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication date should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This First Supplemental Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the document has been considered.

The fee of $180.00 for consideration of this First Supplemental Information Disclosure Statement (37 C.F.R. § 1.17(p)) is included in our check number 36347.

Consideration of this information and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

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Date: Aug. 22, 2002

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| FORM PTO-1449<br><br>FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT | ATTY. DOCKET NO.<br>0942.3910003/BJD/AGU | APPLICATION NO.<br>09/741,664 |
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| | APPLICANT<br>RASHTCHIAN *et al.* | |
| | FILING DATE<br>December 21, 2000 | GROUP<br>1634 |

**U.S. PATENT DOCUMENTS**

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB-CLASS | FILING DATE |
|---|---|---|---|---|---|---|---|
| | AA | | | | | | |
| | AB | | | | | | |
| | AC | | | | | | |
| | AD | | | | | | |
| | AE | | | | | | |
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| | AG | | | | | | |
| | AH | | | | | | |
| | AI | | | | | | |
| | AJ | | | | | | |
| | AK2 | 5,587,287 | 12/24/1996 | Scalice *et al.* | 435 | 6 | 04/07/1994 |

**FOREIGN PATENT DOCUMENTS**

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
|---|---|---|---|---|---|---|---|
| | AL | | | | | | Yes No |
| | AM | | | | | | Yes No |
| | AN | | | | | | Yes No |
| | AO | | | | | | Yes No |
| | AP | | | | | | Yes No |

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

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| | AR | 1 | |
| | AS | 1 | |
| | AT | 1 | |

| EXAMINER | DATE CONSIDERED |
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**EXAMINER**: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.